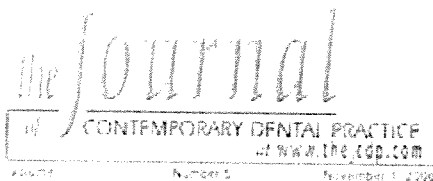


Exhibit R



Correlations Between Two Plaque Indices in Assessment of Toothbrush Effectiveness

MaryAnn Cugini, RDH, MHP, Maureen Thompson, RDH,
Paul R. Warren, LDS



Abstract

Background: The Rustogi et al. Modified Navy (RMNPI) and Turesky et al Modification of the Quigley Hein (TQHPI) plaque indices are commonly used to measure plaque removal. This study evaluated the possible correlations of both indices using data relative to a single use assessment of plaque removal using commercially available toothbrushes.

Methods: Single use crossover study designs have been previously reported. Disclosed plaque was scored pre- and post-brushing using both the RMNPI and the TQHPI. Sixty subjects, with an initial mean RMNPI score of 0.6 or greater, were enrolled and completed the study. No minimum score was required for TQHPI. After the initial scoring, the order for each index was randomized so that each subject was scored with either RMNPI followed by TQHPI or vice versa. Two manual toothbrushes [Oral-B® CrossAction® (CA) and Colgate® Navigator™ (NA)] and one battery-powered brush (Crest® SpinBrush™ Pro) (SBP) were evaluated in the trial. One examiner performed all clinical measurements. Pearson correlations were performed on whole mouth, buccal, and lingual plaque scores for the CA toothbrush.

Results: Strong positive correlations were found between the two plaque indices for pre- and post-brushing scores for the whole mouth and on lingual and buccal surfaces, where Pearson correlation coefficients ranged between 0.963 and 0.995. There was no correlation between the pre-brushing plaque score and the amount of plaque removed by brushing indicating that higher plaque levels before brushing do not necessarily predict that greater amounts of plaque will be removed during toothbrushing. Each toothbrush was found to be safe

and significantly reduced plaque levels after a single brushing (t-test, $p=0.0001$). Significantly greater plaque reductions were found with the CA than the NA and SBP toothbrushes at whole mouth, lingual, and approximal surfaces for both indices (analysis of variance (ANOVA), $p \leq 0.0002$ for all comparisons).

Conclusions: Strong positive correlations were found between two plaque indices (the RMNPI and TQHPI) for pre- and post-brushing scores at whole mouth, lingual, and buccal surfaces as assessed using data from a single use assessment of plaque removal.

Efficacy data from this study demonstrated the CA toothbrush provided superior cleaning when compared to the NA manual toothbrush and SBP battery toothbrush.

Clinical Implications: Two commonly used indices for assessing plaque removal in clinical studies are RMNPI and TQHPI. However, each index differs in the way plaque is scored. This study used both indices to assess comparative toothbrush efficacy and showed a strong correlation between indices for both pre- and post-brushing plaque scores. The result suggests that both indices demonstrate sufficient sensitivity to differentiate toothbrush efficacy.

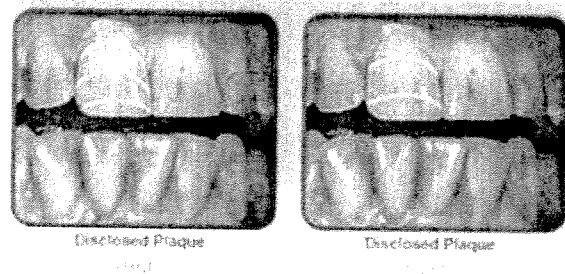
Keywords: Plaque, toothbrush, clinical trial, Rustogi Modified Navy Plaque Index, Turesky Modified Quigley Hein Plaque Index

Citation: Cugini M, Thompson M, Warren PR. Correlations Between Two Plaque Indices in Assessment of Toothbrush Effectiveness. J Contemp Dent Pract 2006 November;(7)5:001-009.

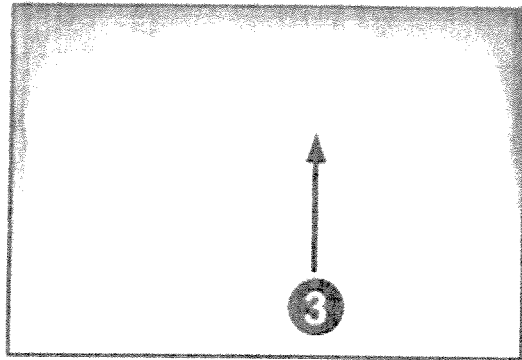
Introduction

Dental plaque is recognized as the primary etiologic agent for the development of dental caries, gingivitis, and periodontal disease.¹⁻⁴ Regular removal of plaque from all tooth surfaces, especially interproximal surfaces, is paramount to the maintenance of healthy oral tissue. The manual toothbrush is the principal device for home care plaque removal, and although mostly effective on flat and occlusal surfaces, it is far from satisfactory in plaque control at interproximal sites where development of gingival disease is most likely.⁵⁻⁷

A key factor in assessing the relative plaque removal performance of different toothbrushes is the ability to quantify the amount and distribution of plaque on tooth surfaces before and after brushing. Of particular importance is the sensitivity of a plaque index to allow estimation of plaque on approximal surfaces and along gingival margins, which represent areas commonly missed during toothbrushing.^{8,9} Two commonly used plaque indices are the Turesky et al Modified Quigley Hein Plaque Index (TQHPI) and the Rustogi et al Modified Navy Plaque Index (RMNPI).¹⁰⁻¹² The TQHPI represents the

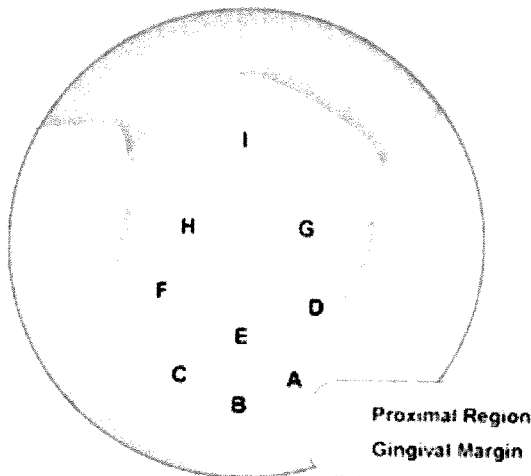


broad surface area of the whole buccal or lingual surfaces while giving focus to the gingival third of the tooth and grades plaque and debris on a scale 0-5 (0=no plaque/debris, 5=plaque covering two-thirds or more of the crown of the tooth) (Figure 1). Modifications of the TQHPI include separating each buccal and lingual aspect into three surfaces (mesial, distal, and mid), using the line angles of the tooth to the contact point bordered by the gingival margin as guidelines for approximal regions, to give a total of six surfaces per tooth. The RMNPI extends the scoring of plaque in approximal (mesial and distal) tooth areas and at the gumline (marginal gingival) region as well as the total tooth. It divides buccal



Plaque

Figure 1. Tooth areas graded by the Turesky et al Modified Quigley Hein Plaque Index.



Tooth area plaque scores are grouped and designated as: Whole mouth = Areas A, B, C, D, E, F, G, H, and I; Marginal (gumline) = Areas A, B, and C only; Approximal = Areas D and F only.

Figure 2. The Rustogi et al Modified Navy Plaque Index.

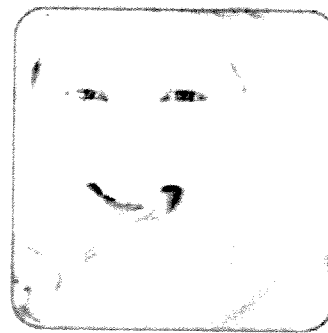
and lingual surfaces into nine areas that are scored for the presence or absence of plaque (Figure 2).

The present study examined the possible correlations between the TQHPI and RMNPI by comparing plaque scores between the indices (pre- and post-brushing) in an examiner-blind, randomized, crossover, single-use study that

evaluated and compared the safety and plaque removal efficacy of two manual toothbrushes and a battery operated brush in a balanced incomplete design.

Methods and Materials

This study was approved by the Institutional BRCL Review Board and conducted at an independent research organization (BioSci Research Canada, Ltd., Mississauga, Ontario). Subjects from the general population of a large metropolitan area, aged between 18 and 70 years and in good general health, were enrolled by local advertisements. Each subject had a minimum of 18 scorable teeth (excluding third molars, teeth with orthodontic appliances, bridges, crowns, or implants) and a whole mouth pre-brushing RMNPI ≥ 0.60 at the initial visit. In addition, subjects were current manual toothbrush users. Reasons for exclusion included any physical limitations that might compromise normal toothbrushing technique, evidence of neglected oral hygiene or major hard or soft tissue lesions or trauma, a medical condition with a requirement of prophylactic antibiotic coverage before dental treatment, and use of antibiotic therapy or anti-inflammatory medications for three or more consecutive days in the previous 28 days. Subjects had to refrain from any elective, non-emergency dental care including prophylaxis during the study. All subjects gave written informed consent, and the protocol was approved by an Institutional Review Board before study initiation.



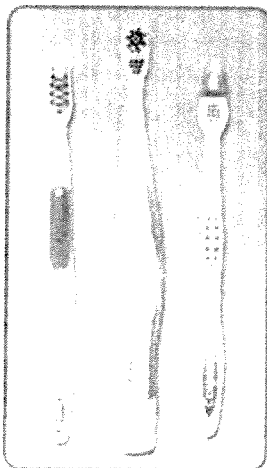
Subjects who had abstained from oral hygiene procedures in the previous 23-25 hours and from eating, drinking, and smoking in the previous four hours received an oral hard and soft tissue examination and plaque assessment. After

disclosing with Chrom-O-Red erythrocin FD&C red number 3 solution (Germiphene Corp., Bradford, Ontario, Canada), plaque was scored using two plaque indices: the TQHPI (Figure 1) and the RMNPI (Figure 2). With the TQHPI, mesial, distal, and mid surfaces of facial and lingual aspects were scored. Scoring was as follows:

- 0 = no plaque/debris
- 1 = separate flecks of plaque at the cervical margin of the tooth.
- 2 = a thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth.
- 3 = a band of plaque wider than 1 mm but covering less than one third of the crown of the tooth.
- 4 = plaque covering at least one third but less than two thirds of the crown of the tooth.
- 5 = plaque covering two thirds or more of the crown of the tooth.

The RMNPI plaque was evaluated as either present or absent (1 or 0) on each of the nine areas of the buccal and lingual tooth surfaces. Whole mouth, marginal, and approximal areas were defined as shown in Figure 2.

Safety assessments were performed on both hard and soft tissues, including the lips, tongue, gingival, sublingual area, inner surfaces of the cheeks, mucobuccal folds, hard and soft palate, and pharyngeal area, as well as cervical areas of all teeth. Parameters observed were color, texture, soft tissue abrasion, and any irregularities and effects on hard tissues and/or dental restorations. Abnormal findings were recorded together with any reported adverse events.



The three toothbrushes tested were two manual brushes: the Oral-B CrossAction (CA) manual #40 soft (Oral-B Laboratories, Boston, MA, USA) and the Colgate Navigator (NA) full head soft (Colgate-Palmolive Company, New York, NY, USA) and the battery-operated Crest SpinBrush Pro (SBP) (formerly distributed by Procter & Gamble, Cincinnati, OH). Following the oral examination and measurement of pre-brushing plaque scores at the first visit, subjects eligible for participation in the study were randomized to use two of the three brushes in one of six separate treatment sequences by subject number in a balanced incomplete block design. Subjects brushed under supervision with their assigned toothbrush and a supplied fluoride dentifrice (Crest[®] Cavity Protection; Procter & Gamble Company, Cincinnati, OH, USA) for a timed period. The fluoride dentifrice was dispensed by the brushing supervisor and was sufficient to cover the area of the toothbrush bristles. No instruction in toothbrushing technique was provided, which reflects normal use following the purchase of these brushes. The oral safety examination and plaque scores by both indices were repeated after brushing. After the initial scoring, the order for each index was randomized so that each subject was scored with either RMNPI followed by TQHPI or vice versa. Subjects used their usual method of oral hygiene for a brief washout period (minimum of four days) and returned to the test facility having refrained from oral hygiene for 23-25 hours and from eating, drinking, and smoking in the previous four hours to brush with the alternately assigned toothbrush. Pre- and post-brushing assessments were repeated.

All clinical measurements were taken by one examiner, who was blind to the study products and treatment group assignments. The examiner was familiar with the indices used and was calibrated for intra-examiner reproducibility.

Data Analysis

The sample size for this study was based on a previous comparative toothbrush study.¹³ Pearson correlations between whole mouth, buccal, and lingual RMNPI and TQHPI scores were investigated using data from subjects assigned the CA toothbrush.

Pre-treatment comparability of all three treatment groups was analyzed for gender using a chi-square test for homogeneity and for age and plaque level using an analysis of variance (ANOVA). Changes from pre-brushing to post-brushing plaque levels within each treatment group were assessed using a paired t-test. Between group changes were assessed using ANOVA with models appropriate for a balanced incomplete block design. Where overall significant group differences were identified, the least-significant-difference method was used to perform pairwise t-tests to identify which groups differed significantly.

Results

Subjects

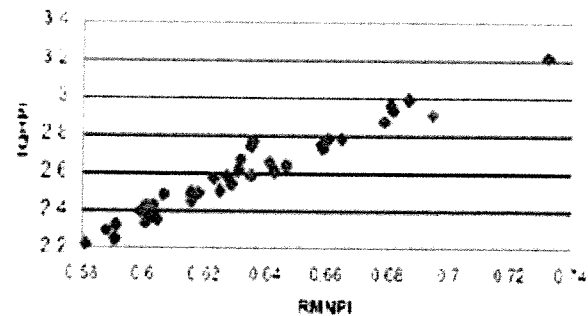
A total of 60 subjects (46 females, 14 males) were enrolled, and all subjects completed the study. Ten subjects were randomly assigned to each treatment sequence group. The mean ages (\pm SD) of each treatment sequence group were as follows: CA/NA=34.9 \pm 11.0; CA/SBP=33.1 \pm 9.5; SBP/CA=34.5 \pm 9.0; SBP/NA=36.0 \pm 9.5; NA/CA=39.0 \pm 10.9; and NA/SBP=35.5 \pm 15.1 years, respectively. The corresponding pre-brushing mean whole mouth RMNPI scores were as follows: 0.63/0.61; 0.64/0.64; 0.65/0.63; 0.64/0.64; 0.64/0.63; and 0.63/0.62. The treatment sequence groups were well balanced, and there was no statistically significant difference between groups in gender, age, or pre-brushing plaque levels ($p > 0.05$).

Correlation Between the Plaque Indices

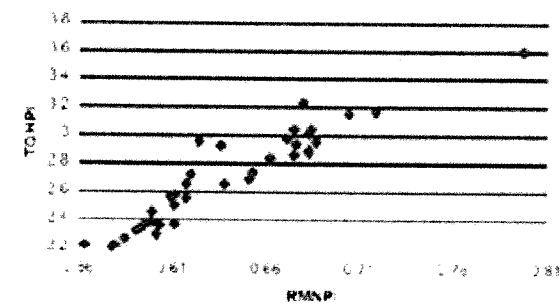
Analysis of the relationship between the two plaque indices (Table 1) revealed a strong positive correlation between RMNPI and TQHPI pre- and post-brushing scores for the whole mouth and on lingual and buccal surfaces where Pearson correlation coefficients ranged between 0.963 and 0.9952. A high level of correlation between RMNPI and TQHPI scores was also apparent for the pre- and post-brushing scores combined (Table 1). Pre-brushing approximal RMNPI scores had values of 1 (presence of plaque) for all subjects and, therefore, the correlation with TQHPI scores was not calculated. When pre-brushing scores between the two indices were correlated for whole mouth, and lingual and buccal surfaces,

the minimum qualifying RMNPI score for study entry of 0.6 or greater corresponded to TQHPI scores of approximately 2.3 or greater (Figure 3). Evaluation of the relationship between pre-brushing plaque scores and change in plaque score after brushing showed no correlation for either index on whole mouth (RMNPI $r=-0.239$; TQHPI $r=0.0453$), lingual (RMNPI $r=-0.672$; TQHPI $r=-0.487$), or buccal (RMNPI $r=0.1828$; TQHPI $r=0.4697$) surfaces (Table 2).

a) Whole Mouth



b) Buccal



c) Lingual

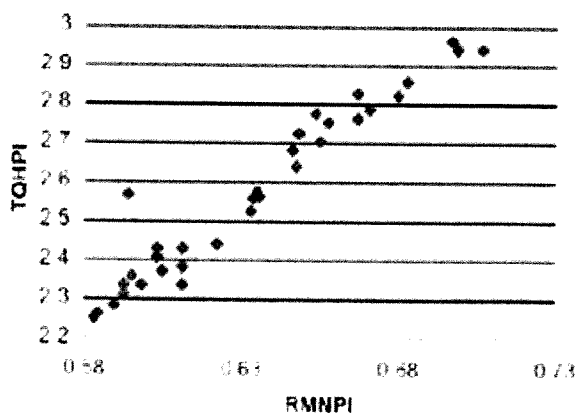


Figure 3. Correlation between pre-brushing RMNPI and TQHPI scores

Plaque Removal Efficacy

Each toothbrush significantly reduced plaque levels on all tooth surfaces after single brushing as measured by both RMNPI and TQHPI scores (Tables 3 and 4). Both indices showed plaque reduction efficacy was significantly greater for the CA compared with the NA and SBP brushes (Tables 3 and 4; Figures 4 and 5). The CA

toothbrush was more effective than both the other brushes in plaque removal from whole mouth, lingual, hard-to-reach approximal surfaces, and the gingival margin. For buccal surfaces, the CA toothbrush removed significantly more plaque than the SBP brush by the RMNPI score but not by the TQHPI.

Table 1. Correlation of RMNPI and TQHPI scores pre- and post-brushing.

Site	RMNPI *	TQHPI *	Correlation
Whole mouth			
Pre-brushing score (n=40)	0.63 ± 0.03	2.59 ± 0.22	0.9755
Post-brushing (n=40)	0.27 ± 0.08	1.14 ± 0.35	0.9912
Pre/Post-brushing combined (n=80)	0.45 ± 0.19	1.86 ± 0.79	0.9952
Lingual			
Pre-brushing score (n=40)	0.63 ± 0.04	2.53 ± 0.24	0.9868
Post-brushing (n=40)	0.41 ± 0.12	1.71 ± 0.51	0.9859
Pre/Post-brushing combined (n=80)	0.52 ± 0.14	2.12 ± 0.57	0.9846
Buccal			
Pre-brushing score (n=40)	0.63 ± 0.05	2.65 ± 0.36	0.9630
Post-brushing (n=40)	0.14 ± 0.09	0.56 ± 0.39	0.9911
Pre/Post-brushing combined (n=80)	0.39 ± 0.26	1.60 ± 1.11	0.9942
Approximal			
Pre-brushing score (n=40)	1 ± 0	2.66 ± 0.26	not calculated**
Post-brushing (n=40)	0.37 ± 0.12	1.22 ± 0.36	0.9466
Pre/Post-brushing combined (n=80)	0.68 ± 0.33	1.94 ± 0.79	0.9661

**Mean plaque scores (±SD) before and after single use.

**No correlation calculated because all pre-brushing RMPI scores = 1.

Table 2. Correlation between pre-brushing score and change from baseline values after brushing.

Site	Plaque index	Pre-brushing score	Post-brushing change from baseline	Correlation
Whole mouth	RMNPI (n=40)	0.63 ± 0.03	0.36 ± 0.06	-0.239
	TQHPI (n=40)	2.59 ± 0.22	1.45 ± 0.28	0.0453
Lingual	RMNPI (n=40)	0.63 ± 0.04	0.22 ± 0.09	-0.672
	TQHPI (n=40)	2.53 ± 0.24	0.81 ± 0.36	-0.487
Buccal	RMNPI (n=40)	0.63 ± 0.05	0.50 ± 0.08	0.1828
	TQHPI (n=40)	2.65 ± 0.36	2.09 ± 0.40	0.4697

Table 3. Brushing changes in mean RMNPI scores (\pm SD).

Site	Toothbrush	Pre-brushing (SD)	Post-brushing (SD)	Mean plaque reduction* (SD)	Between group comparison p-value**
Whole mouth	CA	0.63 \pm 0.03	0.27 \pm 0.08	0.36 \pm 0.06	CA vs. NA, P=0.000*
	NA	0.63 \pm 0.03	0.34 \pm 0.07	0.29 \pm 0.05	CA vs. SBP, P=0.000*
	SBP	0.64 \pm 0.04	0.35 \pm 0.08	0.28 \pm 0.07	NA vs. SBP, P=0.474
Gingival margin	CA	1.00 \pm 0.00	0.48 \pm 0.10	0.52 \pm 0.10	CA vs. NA, P=0.000*
	NA	1.00 \pm 0.00	0.57 \pm 0.10	0.43 \pm 0.10	CA vs. SBP, P=0.000*
	SBP	1.00 \pm 0.00	0.59 \pm 0.11	0.41 \pm 0.11	NA vs. SBP, P=0.214
Approximal	CA	1.00 \pm 0.00	0.37 \pm 0.13	0.63 \pm 0.12	CA vs. NA, P=0.000*
	NA	1.00 \pm 0.00	0.48 \pm 0.11	0.52 \pm 0.11	CA vs. SBP, P=0.000*
	SBP	1.00 \pm 0.00	0.51 \pm 0.14	0.49 \pm 0.14	NA vs. SBP, P=0.3798
Buccal	CA	0.63 \pm 0.05	0.14 \pm 0.09	0.50 \pm 0.08	CA vs. NA, P=0.0678
	NA	0.63 \pm 0.03	0.17 \pm 0.09	0.45 \pm 0.08	CA vs. SBP, P=0.008
	SBP	0.64 \pm 0.06	0.20 \pm 0.11	0.44 \pm 0.10	NA vs. SBP, P=0.3786
Lingual	CA	0.63 \pm 0.04	0.41 \pm 0.12	0.22 \pm 0.09	CA vs. NA, P=0.000*
	NA	0.63 \pm 0.05	0.50 \pm 0.11	0.13 \pm 0.07	CA vs. SBP, P=0.0001
	SBP	0.64 \pm 0.04	0.51 \pm 0.12	0.12 \pm 0.09	NA vs. SBP, P=0.7910

CA=Oral-B CrossAction, NA=Colgate Navigator, SBP=Crest SpinBrush Pro.

* Mean plaque reductions within each group were significant (p=0.0001).

** Overall group differences significant (P=0.0001 for all sites except buccal, P=0.025). Significant P-values were in favour of CrossAction (CA) versus either the Navigator (NA) or SpinBrush Pro (SBP) toothbrushes using pairwise t-tests.

n.s. Non significant.

Table 4. Brushing changes in mean TQHPI scores (\pm SD).

Site	Toothbrush	Pre-brushing (SD)	Post-brushing (SD)	Mean plaque reduction* (SD)	Between group comparison p-value**
Whole mouth	CA	2.59 \pm 0.22	1.14 \pm 0.35	1.45 \pm 0.28	CA vs. NA, P=0.000*
	NA	2.58 \pm 0.22	1.41 \pm 0.31	1.18 \pm 0.24	CA vs. SBP, P=0.0001
	SPB	2.63 \pm 0.25	1.46 \pm 0.34	1.16 \pm 0.28	NA vs. SBP, P=0.7271
Approximal	CA	2.66 \pm 0.26	1.22 \pm 0.36	1.44 \pm 0.30	CA vs. NA, P=0.0002
	NA	2.66 \pm 0.27	1.51 \pm 0.34	1.15 \pm 0.25	CA vs. SBP, P=0.0001
	SPB	2.71 \pm 0.29	1.58 \pm 0.36	1.13 \pm 0.29	NA vs. SBP, P=0.6431
Buccal	CA	2.65 \pm 0.36	0.56 \pm 0.39	2.09 \pm 0.40	overall group difference not significant
	NA	2.60 \pm 0.29	0.69 \pm 0.36	1.92 \pm 0.35	
	SPB	2.68 \pm 0.41	0.77 \pm 0.45	1.91 \pm 0.43	
Lingual	CA	2.53 \pm 0.24	1.71 \pm 0.51	0.81 \pm 0.35	CA vs. NA, P=0.000*
	NA	2.57 \pm 0.31	2.12 \pm 0.49	0.44 \pm 0.26	CA vs. SBP, P=0.0001
	SPB	2.57 \pm 0.27	2.15 \pm 0.52	0.42 \pm 0.32	NA vs. SBP, P=0.9884

CA=Oral-B CrossAction, NA=Colgate Navigator, SBP=Crest SpinBrush Pro.

* Mean plaque reductions within each group were significant (p=0.0001).

** Overall group differences significant (P=0.0001 for all sites except buccal, P=0.025). Significant P-values were in favour of CrossAction (CA) versus either the Navigator (NA) or SpinBrush Pro (SBP) toothbrushes using pairwise t-tests.

n.s. Non significant.

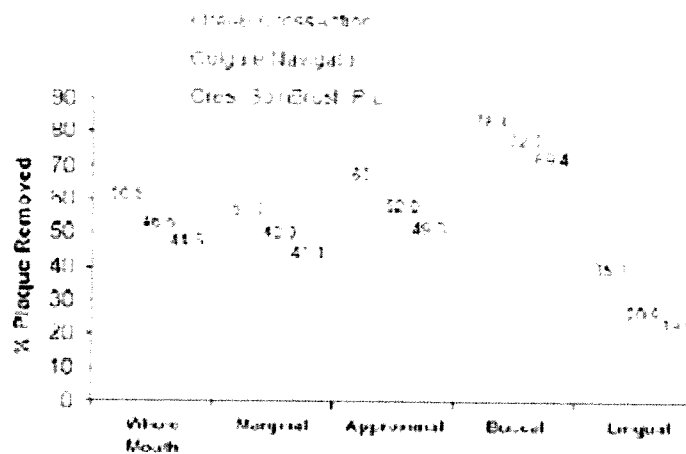


Figure 4. Plaque removal efficacy by RMNPI after single use.

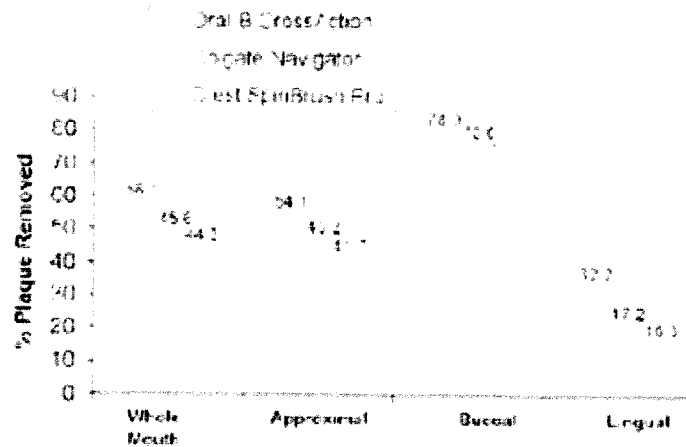


Figure 5. Plaque removal efficacy by TQHPI after single use.

Safety

There was no evidence of any hard or soft tissue trauma associated with the single use of any of the test toothbrushes. No adverse events were reported during the study.

Discussion

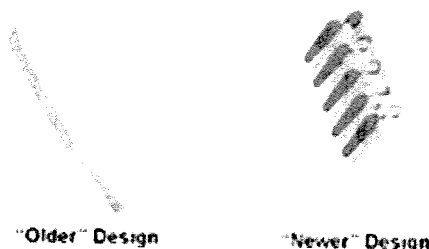
The two different plaque indices used in this study (RMNPI and TQHPI) were well correlated with each other at whole mouth, lingual, and buccal surfaces for both pre-brushing scores and post-brushing scores (Pearson correlation coefficients ranged between 0.9630 and 0.9952). Interestingly, correlation of the pre-brushing scores revealed the minimum qualifying RMNPI score of 0.6 for study enrollment corresponded

to TQHPI scores of approximately 2.3, which relate to moderate plaque levels commonly required for entry into toothbrushing efficacy studies.^{11,12,14,15} There was no correlation between pre-brushing plaque score and change in plaque score after brushing for either index in this study indicating higher plaque levels before brushing did not necessarily predict that greater amounts of plaque will be removed during toothbrushing. Approximal RMNPI scores had pre-brushing values of 1 (presence of plaque) for all subjects and, therefore, the correlation with pre-brushing TQHPI scores was not calculated. Post-brushing approximal RMNPI and TQHPI scores did, however, show a high level of correlation

(Pearson correlation coefficient of 0.9466). In addition to the high level of correlation, both indices showed a high level consistency with respect to product differentiation. CA demonstrated significant differences between products by both indices and to the same level of significance.

Several plaque indices have been assessed and are widely used to determine differences in plaque removal among toothbrushes.¹⁶ The value of plaque indices for comparing toothbrush efficacy was revealed in the present study by the sensitivity of RMNPI and TQHPI in exposing the differences in plaque removal effectiveness between the CA, NA, and SBP brushes. Whole mouth plaque reductions showed a similar pattern and degree for both indices; reductions of 56.9%, 46.6%, and 44.5% by the RMNPI and 56.1%, 45.6%, and 44.3% by the TQHPI after one-minute of brushing with the CA, NA, and SBP brushes, respectively. Corresponding reductions in approximal plaque revealed an apparent disparity (63.1%, 52.0%, and 49.3% by the RMNPI and 54.1%, 43.2%, and 41.7% by the TQHPI) that probably reflects the greater number of surfaces scored with RMNPI, thereby, resulting in a consistently higher percentage of plaque removal compared to TQHPI. Efficient plaque removal at buccal sites for all three brushes was evident with both indices, but TQHPI did not show statistically significant differences for CA compared to NA. This result may be due to the rating method where the TQHPI results reflect the reduction in area of plaque coverage versus presence or absence as scored by RMNPI. With both RMNPI and TQHPI scores the reduction in plaque after a single brushing with the CA was significantly greater than reductions seen with both the NA and SBP brushes, not only at whole mouth and less accessible approximal surfaces but also at the lingual surface. This finding is of relevance because advancements in toothbrush design give the greatest opportunity to enhance plaque removal.¹⁷ Superior plaque

Advancements in Toothbrush Design



reduction efficacy of the CA brush over many other commercially available manual toothbrushes has been demonstrated in a series of examiner-blind crossover studies involving subjects from a general population who used their usual brushing technique; the present findings are in agreement with these studies.^{13,18} Importantly, since both the present and earlier investigations did not involve any alteration in individual brushing technique and employed a brushing time associated with oral hygiene at home (i.e., one minute),¹⁹ it is likely the strong correspondence between the two plaque indices in the present study is relevant to plaque removal in both clinical investigations and home-use situations.

Conclusion

Strong positive correlations were found between two plaque indices (the RMNPI and TQHPI) for pre- and post-brushing scores at whole mouth, lingual, and buccal surfaces as assessed using data from a single use assessment of plaque removal.

Efficacy data from this study demonstrated the Oral-B CrossAction toothbrush provided superior cleaning when compared to the Colgate Navigator manual toothbrush and Crest SpinBrush Pro battery toothbrush.

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Acknowledgements

The single use plaque study was conducted at BioSci Research Canada Ltd, Mississauga, Ontario, CR Goyal, BDS, examiner. The authors thank Dennis King, PhD, STATKING Consulting, Inc., Fairfield, OH, USA for statistical analysis and Jane Mitchell, PhD, MWS, Staffordshire, UK for assistance in preparation of this manuscript.